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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 11 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 83-NC-02. Proposed Section 18 exemption for the use of vinclozolin on peanuts in North Carolina. Submission of March 3, 1983.

FROM: Edward Zager, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief
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TO: Emergency Response Section
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

In our review of February 10, 1983 (E. Zager) we indicated that for a further consideration of this request we will require:

1. Residue data reflecting the proposed use for peanuts, and peanut hulls, vines and hay.
2. A peanut processing study.
3. Metabolism/feeding studies for large ruminants and poultry.
4. Methodology and validation data for vinclozolin and its metabolites in meat, milk, poultry and eggs.

The State of North Carolina has now submitted additional data in support of this request. Residue trials were conducted at four locations in Virginia and one in North Carolina.

Following 2-4 applications at the rate of 0.75 lb. act./A, residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety ranged from <0.05 ppm-0.5 ppm in or on peanuts and from <0.05 ppm-3.2 ppm in or on peanut hulls at PHI's of 13-57 days.

Based on the above data, we estimate that residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 1 ppm in or on peanuts and 5 ppm in or on peanut hulls at 14-day PHI as a result of the proposed use.

No peanut processing study has been submitted. When rape seed, another oil seed crop was processed into oil and coarse meal, a three-fold concentration of residues was observed in the oil. No concentration of residues was observed in the meal. We do not expect any concentration of residues in the soapstock. Translating the data for rape seed to peanuts we estimate that residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 3 ppm in peanut oil and 1 ppm in peanut meal and soapstock at a 14-day PHI as a result of the proposed use. No residue data has been submitted for peanut forage and hay.

Meat, Milk, Poultry and Eggs

There are no large ruminant metabolism studies available. In a rat metabolism study the major metabolite found in the feces was N-(3,5-dichlorophenyl)-2-methyl-2,3,4-trihydroxy butenoic acid amide. For the purposes of this Section 18 exemption we consider the residue of concern in animal tissues and milk to consist of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

The analytical method used to generate residue data for animal tissues and milk involves conversion residues of vinclozolin to dichloroaniline by alkaline hydrolysis, steam distillation, partition into dichloromethane, followed by derivatization with chloroacetyl chloride to form N-(3,5-dichlorophenyl)-chloroacetamide. This derivative is then determined by gas chromatography with an electron capture detector. The method determines vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

Reported recoveries from meat, milk, poultry and eggs fortified with 0.05-2.50 ppm vinclozolin ranged from 77-101%.

In a cattle feeding study two groups of 3 cows each were administered 3 and 15 ppm vinclozolin in the diet for 28 days.

Highest residues were found in liver samples up to 0.6 ppm and 2.3 ppm, respectively. Residues in the muscle ranged up to 0.05 ppm and 0.24 ppm, respectively. Residues in the milk were non-detectable (≤ 0.05 ppm) in the cows administered 3 ppm vinclozolin in their diet and ranged up to 0.19 ppm in the group of cows administered 15 ppm in their diet.

In a poultry feeding study 3 groups of laying hens were administered vinclozolin at 3 ppm, 15 ppm and 30 ppm in their respective diets for 28 days. Residues increased up to 0.08 ppm, 0.31 ppm and 0.76 ppm, respectively in the eggs during the 28-day administration.

In the tissues, highest residues were found in the kidney and liver 0.07-0.10 ppm, 0.39-0.48 ppm and 0.55-0.69 ppm from the respective feeding levels. Residues in other tissues were ≤ 0.05 ppm in the group administered 3 ppm in the diet and ranged up to 0.12 ppm and 0.18 ppm, respectively in the two groups administered higher dietary levels of vinclozolin.

Provided the feed use of peanut vines and hay is restricted, the major feed items involved in this use include peanut meal which may constitute up to 25% of dairy cattle's and 10% of poultry's diet, equivalent to 0.25 ppm and 0.1 ppm vinclozolin, respectively.

Based on the above feeding studies, we estimate that secondary residues of vinclozolin and its 3,5-dichloroaniline containing metabolites will not exceed 0.05 ppm in eggs, milk and the meat, fat and meat byproducts of cattle, goats, hogs, horses poultry and sheep from this use.

Conclusions

1. Residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 1 ppm in or on peanuts, peanut meal and soapstock, 3 ppm in peanut oil and 5 ppm in or on peanut hulls from the proposed use at a 14-day PHI.

2. In the absence of residue data for peanut forage and hay, a restriction against feeding these items to livestock should be imposed on this use.

3. Secondary residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 0.05 ppm in eggs, milk, and the meat, fat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep from the use.

Recommendation

TOX considerations permitting and provided a 14-day PHI and a restriction against feeding treated peanut forage and hay to livestock are imposed on this use, we have no objections to the issuance of this Section 18 exemption.

Appropriate agreements should be made with FDA and USDA regarding the legal status of the treated commodities in commerce.

cc: R.F.
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83-NC-02, Vinclozolin
Section 18 S.F.
TOX

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